



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,453	03/06/2002	Roberto Cecchi	IVD 1135	5554

27546 7590 05/02/2003  
SANOFI-SYNTHELABO INC.  
9 GREAT VALLEY PARKWAY  
P.O. BOX 3026  
MALVERN, PA 19355

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
----------	--------------

1625

DATE MAILED: 05/02/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/070,453

Applicant(s)

CECCHI ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 06 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-12 and 14-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-5,8 and 10-26 is/are rejected.
- 7) ☐ Claim(s) 6,7 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. This application is a 371 of PCT/FR00/02482. A preliminary amendment was filed.

Claim 13 has been canceled. Claims 1-12, 14-26 are pending.

2. It is noted that both PCT application and the priority document are non-English. Copies of such documents are not found in the file, neither were certified translations submitted of record. Therefore, the priority benefit of any of the prior filing can not be granted at this time.

3. Claims 12, 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Please note that claims 12, 14-19 are drawn to pharmaceutical compositions without dosage limitation. Thus the claims are self conflicting since a pharmaceutical composition must not be either ineffective or toxic. It is recommended that the dosage of "therapeutically effective amount" be incorporated into the claims.

Claims 20-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Initially, it is noted that the method are drawn to  $\beta_3$ - agonist action. The  $\beta_3$  without proper identification is unclear of what is the action site. It is recommended that adrenergic  $\beta_3$  receptor agonist be explicitly pointed out.

Further, it is not clear "what" is the claimed scope encompassing treating pathologies that are "improved". A pathology can be treated by reverse the pathology i.e. treating the etiology of the pathology or disease, or the "symptom" of a pathology can be relieved by treatment i.e.

Art Unit: 1625

fever of a cold. It is unclear what does the scope of "*improved*" is referring to. It is recommended that specific disease/pathology be pointed out and how such pathology can be changed be incorporated i.e. treating irritable bowel syndrome by an agonistic activity of the compound on the adrenergic  $\beta_3$  receptor on colon smooth muscle.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

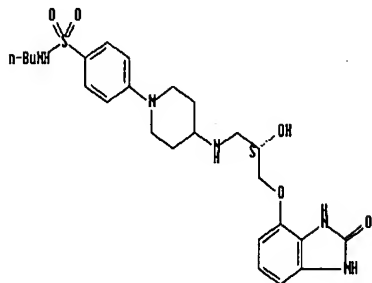
(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 1, 10-11, 12, 20 are rejected under 35 U.S.C. 102(a) (e) or (g) as being anticipated by Sum et al. US 6,444,685.

The Sum reference is a 102(a) reference (publication date) against the instant application date, a 102(e) reference (provisional date) against the instant application date and a 102(g) reference against the instant 371/PCT application date.

Sum et al. '685 disclosed compounds anticipated the claims and one structure is delineated as following :

Art Unit: 1625



which anticipate claim 1 when A is formula (a), Y<sub>1</sub> and Y<sub>2</sub> are NH, n and m are 0, X is CH, R<sub>2</sub> is SO<sub>2</sub>NR<sub>3</sub>R<sub>4</sub>, R<sub>3</sub> is H, R<sub>4</sub> is butyl, thus, anticipated every element of the claim. This compound (see claim 4, col. 66, line 7-9) it is composition and method of inhibiting type II diabetes, atherosclerosis etc. (see claims 5-10) anticipated the instant claims.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8, 10-11, 14-17, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sum et al. '685 in view of Steffan et al. US 6,506,901.

Determination of the scope and content of the prior art (MPEP §2141.01)

Sum et al. '685 disclosed compounds that anticipated the claims which were pointed out supra. Broadly, Sum et al. '685 disclosed variations of compounds wherein the benzimidazolone can be other aromatic moieties see col. 65-69 claim 4 and the X is CH.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Sum et al. '685 disclosed all the elements of the claims **except** the X is N aromatic ring of the instant claim were not found. Steffan et al. '901 is analogous art wherein similar compounds have been disclosed for treating type II diabetes. Steffan et al. '901 taught the variation of Sum in R<sub>1</sub> being aromatic and particularly exemplified that both phenyl and pyridyl are optional choices for such compounds (see col.149-150).

Art Unit: 1625

*Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)*

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references placed the generic teaching of analogous compounds in the possession of artisan in the field. One in possession of the above references would be motivated to employ the pyridinyl moiety (Steffan '901) wherein the phenyl has been employed (Sum '685) **because** the modification of a *proven* compound using *attributes* of another proven compound having analogous activity is prima facie obvious. With the particular side by side exemplification of switching pyridinyl moiety with phenyl moiety (see Steffan '901) the explicit suggestion and reasonable expectation of success of such modification has been disclosed in the prior art.


6. Claims, 6-7, 9, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Compounds wherein A is formula (b) were neither anticipated nor rendered obvious by the art of record because although both Sum '685 and Steffan '901 disclosed generically that A can be pyridyl (R1 for '685, R for '901) no guiding examples were found. In re Baird 29 USP!2d 1550.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

OACS/Chang  
April 28, 2003

  
Celia Chang  
Primary Examiner  
Art Unit 1625